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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,354	01/14/2004	Bradley P. Glassman	025562.0012-US01	3208

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EXAMINER	
HOWARD, SHARON LEE	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 01/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,354	GLASSMAN ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The finality of the rejection of the last Office action is withdrawn and prosecution of this application has been reopened. Receipt of the Response after final, the IDS and the Remarks filed on 10/28/05 have been acknowledged by the examiner. Applicant please note that the documents on the IDS form have been considered and initialed. Claims 1-13 remain pending.

DETAILED ACTION

Specification

The amendment filed 10/28/05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant fail to provide support for "urea as the sole active antifungal ingredient" in the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-13 remain rejected under 35 U.S.C. 103(a) as being unpatentable over the Sun (WO 96/19186) document in view of Chodosh (U.S. Patent No. 5,661,170).

The WO '186 document teaches a method of treating fungal diseases in nails comprising administering to the nail, a composition comprising (see abstract, page 7, lines 9-20) urea in the amount from about 1% to about 50% (page 6, lines 33-37, bridging page 7, lines 1-5, page 10, lines 41-47), an antioxidant consisting of 10.0% of N-acetyl-1-cysteine, 3.0% of mineral oil (see Formulation D – Formulation K on pages 29-31).

The WO '186 document does not particularly teach Vitamin E.

However, Chodosh teaches antimicrobial compositions and methods for using said compositions for treating bacterial infections of the nails or for treating onychomycosis, comprising vitamin E (see col.5, line 62) which is an antioxidant known for protecting cells from oxidation, including a fatty alcohol such as oleyl alcohol and another ingredient consisting of urea (col.6, lines 6-8). The document discloses that it is known in the art that the compositions can be applied as a gel, lotion or as a cleanser, as well as an ointment, salve or as a paste (col.7, lines 28-30 and at line 37).

Both references teach a composition comprising urea, an antioxidant, mineral oil and a fatty alcohol which is known for treating onychomycosis or bacterial infections of the nails. It is *prima facie* obvious to combine two compositions each of which is taught

by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. *(See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).*

One having ordinary skill in the art would have been motivated to prepare a third composition by including Vitamin E in the Sun document, because a third composition can be used for the same purpose for treating bacterial infections or fungal diseases of the nails, and one would expect to achieve similar beneficial results It would therefore have been obvious to combine the teachings of Sun in view of Chodosh.

The expected result would be to provide a method for treating onychomycosis, comprising applying to a nail, a composition comprising urea, Vitamin E and an excipient.

Response to Arguments

Applicant's arguments filed 10/28/05 have been fully considered but they are not persuasive. Applicant argues that urea is not even listed among "antifungal drugs that can be sued in the invention" described in the Sun PCT (page 7, line 35 to page 8, line 5). Nowhere in the Sun PCT is there a recognition that urea can be an effective antifungal ingredient, much less that it can be the sole active antifungal ingredient in a composition effective for treating onychomycosis.

Thus, in contrast to the claimed invention, the Sun PCT does not teach or suggest urea as the sole active antifungal ingredient in a composition effective for treating onychomycosis, or that the urea is present in an amount therapeutically effective for treating onychomycosis. The language "urea as the sole active antifungal

ingredient" excludes itraconazole, ketoconazole, miconazole nitrate, and any of the other "antifungal drugs" listed in the Sun PCT from compositions employed in methods of the present invention. The Chodosh patent also does not teach or suggest using urea as the sole active antifungal ingredient in effectively treating onychomycosis. Nowhere in the Chodosh patent is there any mention of "urea" as opposed to the preservatives "imidazolidinyl urea" and "diazolidinyl urea," much less any mention of urea as an effective antifungal ingredient. Thus, the independent claims patentably distinguish the present invention over the Sun and Chodosh documents, whether those documents are taken individually or in combination. Neither the Sun PCT nor the Chodosh patent would have caused one of ordinary skill in the art to think that urea could be used as the sole active antifungal ingredient in a composition therapeutically effective for the treatment of onychomycosis.

In response to applicant's arguments, the Sun PCT and the Chodosh patent teaches treating onychomycosis or bacterial infections of the nails. It is the position of the examiner that the burden is shifted to applicant to show some unusual result.

Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the submission under 37 CFR 1.129(a). See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard

Sharon Howard
November 15, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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